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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,134	03/11/2004	Gregory H. Altman	032794-054911-CIP	6963
50828	7590	02/08/2008		
DAVID S. RESNICK 100 SUMMER STREET NIXON PEABODY LLP BOSTON, MA 02110-2131			EXAMINER NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1657	
			MAIL DATE	DELIVERY MODE
			02/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/800,134

**Applicant(s)**

ALTMAN ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-49 is/are pending in the application.
- 4a) Of the above claim(s) 32-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to: See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

A response submitted 10/31/07 presented arguments and a 37 CFR 1.132 Declaration, and did not amend the claims.

Claims in the application are 1, 2 and 4-49.

Claims 32-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 9/6/06.

Claims examined on the merits are 1, 2 and 4-31.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support is not found in the specification for "that retain their  
5 native protein structure and have not been dissolved and reconstituted" in claim 1.

#### ***Response to Arguments***

The response urges that paragraph 0021 discloses "In a preferred embodiment, the sericin-extracted silkworm fibroin fibers retain their  
10 native protein structure and have not been dissolved and reconstituted." Paragraph 0022 is also cited as disclosing the fibers are non-recombinant and have not been dissolved and reconstituted.

However, paragraphs 0021 and 0022 are directed to a preferred embodiment where sericin-extracted silkworm fibroin fibers are used.  
15 Claim 1 is now using "native protein structure and have not been dissolved and reconstituted" in a broader context by not requiring the preferred embodiment where the fibers having native protein structure and not being dissolved and reconstituted are from a silkworm.

#### ***Claim Rejections - 35 USC § 103***

20 Claims 1, 2 and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al (7,285,637), and if necessary in view of Li et al (6,303,136) and Takezawa et al (5,736,399).

The claims are drawn to a fabric comprising a yarn comprising one or more sericin-extracted fibroin fibers that retain their native

protein structure and have not been dissolved and reconstituted, and that are biocompatible and non-randomly organized. The yarn promotes ingrowth of cells and is biodegradable.

Armato et al disclose producing non-woven silk fibroin fabrics for use as a cell culture scaffold by degumming silk fibroin to remove sericin, treating with formic acid to break disulfide bonds, and removing the formic acid by evaporation to obtain the fabric (Example 1, col 4, lines 34-50). The breaking of disulfide bonds results in chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells (col 4, lines 21-25). Armato et al further disclose that it is known to use silk fibroin as a cell culture matrix (col 2, lines 4-17), and that textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers in order to obtain a flexible fabric (col 2, lines 20-22).

Li et al disclose attaching cells to a filamentous matrix that can be made from various materials including silk (col 2, line 49 and col 4, line 18).

Takezawa et al disclose using a silk mesh as a culture carrier (col 5, lines 56-60).

It would have been obvious to omit breaking disulfide bonds as disclosed by Armato et al if the result of breaking the bonds is not desired, i.e. providing chain fragments which can serve as specific cellular recognition sites promoting attachment and growth of cells since Armato et al disclose that it is possible to using merely use

degummed silk fibroin fibers to obtain a flexible fabric. It is clear from Armato et al (col 2, lines 20-22) that fabric can be obtained without breaking the bonds, and omitting breaking the bonds would have been expected to simplify the process and be an advantage. To  
5 substitute the advantage of simplification for the advantage of obtaining chain fragments having cellular recognition sites promoting attachment and growth of cells would have been within the ordinary skill of the art. Li et al disclosing attaching cells to a matrix that can be made of silk and Takezawa et al using a silk mesh as a culture  
10 carrier without a requirement for breaking bonds, if needed, would have further suggested that breaking bonds as disclosed by Armato et al can be omitted if the function of breaking bonds is not desired. The conditions of dependent claims would have been matters of obvious choice in view of the disclosures of the references. The parent  
15 application does not antedate Armato et al since the presently claimed invention is not disclosed in the parent application.

#### ***Response to Arguments***

The argument in the response and declaration that Li et al uses a non-degradable matrix does not apply to Armato et al since the fabric  
20 of Armato et al is degradable. The argument in the response and declaration that O'Brien dissolves silk protein and reconstitutes does not apply to Armato et al since Armato et al does not dissolve and reconstitute the silk protein. Breaking disulfide bonds as disclosed by Armato et al does not completely dissolve the fibers, and fibers

exist after treating the fibers with formic acid. Furthermore, Armato et al suggest that fabric can be produced by weaving merely degummed silk fibroin fibers.

#### ***Double Patenting***

5        Claims 1, 2 and 4-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,902,932 B2 in view of Armato et al.

      The claims of the patent require a silk-fiber-based matrix composition comprising sericin-extracted silkworm fibroin fibers.

10       Armato et al is described as above.

      It would have been obvious to provide the matrix of the claims of the patent as a fabric as suggested by Armato et al disclosing forming fabric from sericin-extracted fibroin fibers. The conditions of dependent claim would have been matters of obvious choice in view of  
15 the patent claims and Armato et al. The claims of the patent do not require dissolving and reconstituting.

#### ***Response to Arguments***

      The arguments directed to O'Brien do not apply to Armato et al for reasons set forth above.

#### ***Conclusion***

20       Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For  
10 more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system,  
15 call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657

DMN  
2/2/08